REMARKS

Claims 1 and 6 have been amended to limit the additive to at least one monoterpene ketone, and, therefore, claim 4 has been cancelled.

It is believed the present amendment obviously places the application in condition for allowance. At the least, it should be entered for the purpose of appeal as it raises no new issues.

The error in claim 15, resulting in a 35 U.S.C. 112, second paragraph rejection, obviously was merely clerical and has now been corrected.

The rejections based on Baker et al in view of Yamaguchi et al and Majeti and on that combination further in view of Brisken et al and DeFoney et al are respectfully traversed.

The subject matter of the amended claims now solely concerns transdermal therapeutic systems containing nicotine and in the form of a patch and containing at least one monoterpene ketone in order to improve the odor caused by nicotine and as a permeation enhancer for the nicotine. Systems comprising the essential oils of mint species and, thus, menthol or other monoterpene alcohols are now excluded from the scope of the claims.

Baker et al teaches methods and therapeutic systems for smoking cessation. The systems comprise nicotine as a drug. Baker et al discloses patches for transdermal delivery and distinguishes between monolithic systems and reservoir

systems. Monolithic systems are described in detail in col. 8, line 9 to col. 11, line 14. Then reservoir systems are discussed in detail (col. 11, line 40 to col. 14, line 31). There is no disclosure with respect to the use of essential oils for the drug-containing matrix layer or reservoir in these paragraphs.

Baker further teaches transmucosal drug delivery and names as oral dosage forms lozenge, capsule, gum, tablet, suppository, ointment, gel, pessary, membrane, and powder (col. 16, lines 9 to 15). A nicotine lozenge is discussed in detail beginning in col. 17, line 53, and in col. 20, lines 26 to 37. The addition of a flavorant to a lozenge is disclosed. 1-Menthol and carvone are named among the examples. In addition, examples 33, 34 and 35 disclose the use of flavorants. However, these examples concern capsules, lozenges and tablets. None of the examples concerning transdermal patches mentions essential oils or flavorants.

It is respectfully submitted that the rejections are fatally flawed. They do not comply with 37 CFR 1.104(c)(2), namely, "When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable." The Examiner states that in Baker et al "The adhesive matrix layer comprises nicotine and essential oils." The Examiner is respectfully requested to comply with 37 CFR 1.104(c)(2) by citing by columns(s) and line(s) where Baker et al discloses an adhesive matrix layer comprising, in addition to nicotine, an essential oil. In the

same paragraph the Examiner asserts "the formulation can be made into transmucosal and transdermal formulations." The only administration form disclosed by Baker et al which contains essential oils are lozenges, the sucking of which is a specific form of transmucosal administration. The Baker et al inventions are "methods comprising the transdermal administration of nicotine in combination with the transmucosal administration of nicotine to provide additional periodic doses of nicotine." (Col. 1, lines 9-13). Thus, Baker et al. discloses transdermal and transmucosal not as equivalent modes of administration but as complementary modes of administration. Moreover, nowhere does Baker et al suggest that all transmucosal forms are equivalent. Baker et al discloses essential oils only as flavorants in lozenges, capsules and tablets (Col. 2, lines 26-36 , cited by the Examiner, and Examples 33, 34, 35) To support his above quoted holding, the Examiner is respectfully requested to comply with 37 CFR 1.104(c)(2) by citing by column(s) and line(s) where Baker et al discloses that flavored lozenge, capsule and tablet formulations and transdermal administration formulations are interchangeable.

Yamaguchi et al discloses percutaneously administrable patch preparations and discloses that the patches may contain particular absorbefacients such as 1-menthol and mentha oil (col. 4, lines 51-53). Absorbefacients or so-called penetration enhancers are specific compounds that increase the skin permeability

of a specific drug. In transdermal therapeutic systems a specific combination of drug and enhancer is required to achieve the desired and therapeutically sufficient permeation rate. Thus, the disclosure that menthol might be a permeation enhancer for nicotine does not suggest that monoterpene ketones will function likewise. Thus, the teaching of 1-menthol or of an essential oil containing 1-menthol does not suggest to the skilled artisan that monoterpene ketones might be used as well.

Majeti suggests to add an essential oil or aromatic alcohols or aldehydes contained therein to a transdermally or transmucosally administrable composition containing nicotine as a drug and discloses in example II a buccal dosage form comprising 10%-wt of a flavoring within its drug reservoir. Neither Majeti discloses nor makes obvious that monoterpene ketones may be used to enhance percutaneous penetration of nicotine and, simultaneously, improve the odor of a transdermal administration system.

It is, therefore, believed the application is now in condition for allowance and that action is earnestly solicited.

A one month extension of time is hereby requested for which please charge the government fee of $110.00 to Deposit Account No. 10-1250. Please charge any fee deficiency or credit any overpayment to the same deposit account.

Respectfully submitted,

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APPENDIX I

AMENDED CLAIMS WITH AMENDMENTS INDICATED THEREIN BY BRACKETS AND UNDERLINING

1. (Thrice Amended) Transdermal therapeutic system comprising a backing layer, at least one nicotine-containing layer or zone, and an additive comprising [spearmint oil or] at least one monoterpene ketone [contained in spearmint oil], wherein the content of at least one monoterpene ketone in the nicotine-containing layer or zone is 0.1 to 5.0%-wt of the weight of the layer or zone.

6. (Thrice Amended) Process for masking an unpleasant smell, caused by the presence of nicotine, comprising adding to a nicotine-containing layer or zone of a nicotine-containing transdermal therapeutic system, 0.1 to 5.0%-wt, based on the weight of the layer or zone, of [at least one odor- improving substance, said substance being spearmint oil or] at least one monoterpene ketone [contained in spearmint oil].

15. (Twice Amended) Transdermal therapeutic system according to claim [5]1, wherein the content of the at least one monoterpene ketone in the nicotine-containing layer or zone is 0.5- 2%-wt of the weight of the layer or zone.